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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,783	08/07/2001	Jacky G. Duchamp	ACSC-60113	5784

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/924,783	<b>Applicant(s)</b> DUCHAMP, JACKY G.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,6-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-9, 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 16, 2005 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bazell et al., 3,884,242.

Bazell et al. discloses the invention substantially as claimed. More specifically, Bazell et al. discloses a balloon catheter having a distal end, the balloon catheter comprising:

an elongated catheter shaft (2) having a proximal end, a distal end, a proximal shaft section, a distal shaft section, an inflation lumen (9), and a guidewire receiving

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lumen (29) extending along at least a portion thereof, the guidewire receiving lumen being in communication with a port at the catheter distal end (see fig 3);

a balloon (16) on the catheter distal shaft section, having an interior in fluid communication with the inflation lumen, proximal and distal ends, a proximal shaft section, and a distal shaft section adhesively secured to the catheter shaft (col. 8, lines 6-12 and lines 47-49), the balloon distal shaft section having an outer surface tapering distally (see distal portion of 16 in fig. 3); and

a distal tip member (19) having proximal-most end (22) adhesively secured to the balloon distal shaft section (col. 8, lines 6-8, disclosing that tip 19 includes proximal edge 22, and lines 45-61, disclosing that an adhesive may be used to bind cuff member (i.e., member 16) to the proximal end of tip 19 (i.e., proximal edge 22)), and distal-most end (26), a lumen in fluid communication with the catheter shaft guidewire receiving lumen (see fig. 3), and a proximal portion (20) adhesively secured to the balloon distal shaft section and the catheter shaft (col. 7, lines 64-67.)

Bazell however does not disclose an outer surface tapering distally to a smaller outer diameter from the proximal end of the distal tip member toward the distal end of the distal tip member, nor that the distally tapering outer surfaces of the balloon distal shaft section and the distal tip member are aligned and taper at the same angle.

With respect to an outer surface tapering distally, although Bazell does not mention that the proximal edge 22 has a wall thickness that is thicker than the distal portion of flange 20, Bazell teaches the following. Bazell teaches that the thickness of the tip flange portion 20 may have a wall thickness thinner than the distal portion of

flange 20 or of uniform wall thickness and that *this wall thickness may be varied to provide for smooth transition* between the tip and the body portion 2 or the cuff assembly 12, (see col. 8, lines 38-45.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the proximal edge 22 with a wall thickness that is thicker than the distal portion of flange 20 (i.e., a taper in the distal direction) because Bazell teaches that this wall thickness may be varied to provide for smooth transition between the tip and the body portion or the cuff assembly, as would be desirable for insertion of a catheter into a patient.

Furthermore, it would have been an obvious matter of design choice to have the outer surface of the balloon distal shaft section and the distal tip member be aligned and taper at the same angle since such a modification would have involved a mere change in the size or shape of a component. A change in size or shape is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

2. Claims 1, 3, 6-9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazell et al., 3,884,242, in view of Inoue, 5,100,386.

Bazell discloses the invention substantially as claimed (see above), except for an inner tubular member disposed within at least a portion of the outer tubular member inflation lumen and defining at least in part a guidewire receiving lumen, the guidewire

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receiving lumen being in communication with a port at the catheter distal end. (Bazell however does disclose a guidewire receiving lumen (29) and an inflation lumen (9).)

Inoue also discloses a balloon catheter having an inflation lumen and a guidewire lumen. Inoue discloses an inner tubular member (14) disposed within at least a portion of the outer tubular member inflation lumen (18) and defining at least in part a guidewire receiving lumen (see column 4, lines 22-24, and figure 1), the guidewire receiving lumen being in communication with a port at the catheter distal end (see figure 1).

It would have been obvious to one of ordinary skill in the art to modify the Bazell catheter to have the configuration of the inflation lumen and guidewire lumen as taught by Inoue as well-known, conventional configurations for an inflation lumen and a guidewire lumen.

As to the following claims, Bazell discloses the following limitations.

As to claim 2, the catheter shaft (2) extends distally beyond the balloon distal end, see Figure 7.

As to claim 3, the tip member proximal end forms a butt-joint with the balloon distal shaft section, see column 10, lines 35-37, and see column 12, lines 39-40.

As to claim 11, the adhesive for forming the adhesive seal between the balloon distal shaft section and the catheter shaft extends along the length of the balloon distal shaft section, see column 7, lines 42-50, and see reference number 17 and 17', in Figures 3 and 7.

As to claim 12, the adhesive is capable of being cured, see column 7, lines 64-67.

As to claims 13 and 14, Bazell et al. discloses the step of curing the adhesive to form the catheter assembly in column 7, lines 42-47. Also, the tip member is bonded to the balloon distal shaft section, see column 8, lines 46-57, and see also column 7, lines 42-51 and column 5, lines 37-38.

As to claims 6-9, Bazell et al. does not disclose the length that the distal end of the catheter shaft extends distally beyond the balloon distal end, nor the length that the proximal end of the tip member extends distally over the catheter shaft as claimed by Applicant. However, Bazell et al. teaches that various modifications within the scope of the invention can be made by one of ordinary skill in the art without departing from the spirit thereof, see column 14, lines 5-8. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Bazell et al. device with the various lengths as claimed by Applicant, as modifications that are within the scope of the invention as taught by Bazell et al. as would be necessary for a particular medical use.

### ***Response to Arguments***

Applicant's arguments filed September 16, 2005 have been fully considered but they are not persuasive.

Applicant asserts on pages 7 to 8 that the distal portion of 16 in Figure 3 is spaced above the surface of the shaft and is not itself bonded to the shaft. This is not persuasive because distal portion 16 is bonded to the shaft by element 17 (see col. 7, lines 42-47.)

Applicant also asserts that changing the Bazell catheter such that the distal taper is aligned and tapering at the same angle as the distal end of the balloon would not have been an obvious matter of design choice and is not a mere change in the size and shape of the component but requires a change in the relationship of the tip and balloon relative to one another. Applicant argues that it would require a change in the diameter of the underlying section of the catheter shaft and a change in the length of the distal portion of 16. This is not persuasive because Bazell teaches that the thickness of the tip flange portion 20 *may be varied to provide for smooth transition* between the tip and the body portion 2 or the cuff assembly 12, (see col. 8, lines 38-45.) Thus, a change in the thickness of tip flange portion 20 is specifically taught and a smooth transition between the tip and body portion 2 or the cuff assembly would encompass tapering tip flange portion 20 at the same angle as the distal end of the balloon. A change in the catheter shaft or length of the distal portion of 16 would not be required.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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10/14/05